UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEVA PHARMACEUTICALS, INDUSTRIES, LTD., et al.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 04-1416 (RBW)
FOOD AND DRUG ADMINISTRATION, et al.,	)	
Defendants.	)	

MEMORANDUM OPINION

The plaintiffs filed this action to challenge a decision by the Food and Drug Administration ("FDA"), which permits the sale of brand generic drugs[1] during the generic exclusivity period provided for in 21 U.S.C. § 355(j)(5)(B)(iv)(I). Verified Amended Complaint ("Compl.") ¶¶ 119-24.[2] The parties have filed cross-motions for summary judgment. Currently before the Court are (1) the Plaintiffs' Memorandum of Law in Support of Their Motion for

[1] The Court's use of the terms "brand generic drugs" or "authorized generic drugs" references generic drugs that are put on the market by the holder of a New Drug Application ("NDA") as opposed to a "ANDA generic drug," which is put on the market by the holder of an Abbreviated New Drug Application ("ANDA").

[2] This case has a complicated procedural history. On August 20, 2004, the plaintiffs filed a one-count complaint against the FDA seeking the same relief they seek in the present motions. However, on October 8, 2004, the plaintiffs filed an amended nine-count complaint, which joined Pfizer, Inc. and Greenstone, Ltd. as defendants. On this same date, the plaintiffs also filed a motion for a temporary restraining order, a motion for a preliminary injunction, and a motion for summary judgment. On October 13, 2004, this Court conducted a hearing on the plaintiffs' motion for a temporary restraining order and orally denied the motion at the conclusion of the hearing. Shortly after the hearing, the plaintiffs voluntarily dismissed Pfizer, Inc. and Greenstone Ltd. as defendants and all claims pertaining to those defendants, thus leaving only the federal defendants as parties to the action. However, on October 19, 2004, Greenstone and Pfizer filed a motion to intervene, which this Court later granted. On October 21, 2004, the plaintiff voluntarily dismissed the second claim for relief against the FDA. At the conclusion of the foregoing procedural maneuvering by the parties, only one count of the amended complaint remained and the parties began the process of preparing and filing dispositive motions, which are now ripe for resolution by the Court.

Partial Summary Judgment ("Pls.' Mem."); (2) the Federal Defendants' Memorandum in Support of Motion to Dismiss Amended Complaint or, in the Alternative, for Summary Judgment; and in Opposition to Plaintiffs' Motion for Partial Summary Judgment (Defs.' Mem.); and (3) the Memorandum of Law in Opposition to Defendants' Motion to Dismiss and in Further Support of Plaintiffs' Motion for Summary Judgment ("Pls.' Reply").[3] For the following reasons, this Court will grant the federal defendants' and the intervenor defendants' motions for summary judgment and deny the plaintiffs' motion.

I. Statutory Scheme

Prior to the passage of the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et. seq., commonly referred to as the Hatch-Waxman Amendments, all drug manufacturers—brand-name and generic—were required to conduct controlled human clinical studies to demonstrate that the drug that they wanted to introduce into the market was safe and effective. Allergan, Inc. v. Alcon Lab., Inc., 324 F.3d 1322, 1325 (Fed. Cir. 2003). This requirement delayed the entry into the market of both new drugs and generic versions of such drugs. Id. The Hatch-Waxman Amendments sought to address this situation by striking "a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of

[3] The Court also has before it (1) the Defendant-Intervenors Pfizer Inc.'s and Greenstone Ltd.'s Motion to Dismiss Based on Plaintiffs' Failure to State a Claim Upon Which Relief can be Granted ("Def.-Intervenors' Mem."); (2) the Plaintiffs' Memorandum of Law in Opposition to Defendant-Intervenors Pfizer Inc.'s and Greestone Ltd.'s Motion to Dismiss Based on Plaintiffs' Failure to State a Claim Upon Which Relief can be Granted ("Pls.' Opp'n to Def.-Intervenors' Mem."); and (3) the Defendant-Intervenors Pfizer Inc.'s and Greenstone Ltd.'s Memorandum in Opposition to Plaintiffs' Motion for Summary Judgment and Reply in Further Support of Motion to Dismiss ("Def.-Intervenors' Reply"). Because both the federal defendants and the defendant-intervenors raise essentially the same arguments, the Court will cite primarily to the papers submitted by the federal defendants for clarity and conciseness.

those drugs to the market.'" Allergan, 324 F.3d at 1325 (citing Andrx Pharms., Inc. v. Biovail Corp., 276 F.3d 1368, 1371 (Fed. Cir. 2002)). Under the Hatch-Waxman Amendments, only companies seeking to market a drug that has never been approved for use in the United States are required to submit a New Drug Application ("NDA"). A NDA is required to contain scientific data demonstrating the safety and effectiveness of the new drug. 21 U.S.C. § 355(a), (b), (c). However, companies seeking to market a generic drug of a previously approved drug no longer need to conduct human clinical tests. Instead, the generic drug manufacturer can submit an Abbreviated New Drug Application ("ANDA") demonstrating, among other requirements, that the generic version of the drug is the bioequivalent to the NDA approved version of the drug. 21 U.S.C. §§ 355, 360cc; 35 U.S.C. §§ 156, 271, 282.

The approval of an ANDA depends, in part, upon the applicant submitting "a certification . . . with respect to each patent which claims [a] listed drug [previously approved by the Secretary of Health and Human Services ("HHS") for safety and effectiveness or whose approval has been withdrawn or suspended] or which claims a use for such a listed drug for which the applicant is seeking approval . . . ." 21 U.S.C. §§ 355(j)(2)(A)(vii), 355(7). In addition, the certification must state one of the following:

> (I) that the required patent information relating to such patent has not been filed;
> (II) that such patent has expired;
> (III) that the patent will expire on a particular date;
> (IV) that such patent is invalid or will not be infringed upon by the drug for which approval is sought.

35 U.S.C. § 355(j)(2)(A)(vii). "If [a] certification is made under paragraph I or II indicating that patent information pertaining to the drug or its use has not been filed with the FDA or that the patent has expired, approval of the ANDA may be made effective immediately." Barr Labs. Inc.

v. Thompson, 238 F. Supp. 2d 236, 240 (D.D.C. 2002) (citing 21 U.S.C. § 355(j)(5)(B)(i)). A paragraph III certification indicates that the applicant seeks approval to market the drug only after the applicable patent has expired. 21 U.S.C. § 355(j)(5)(B)(ii). When the ANDA contains a paragraph IV certification, the applicant must also provide notice of the paragraph IV certification to the NDA holder and the patent owner, and describe the factual and legal basis for the applicant's opinion that an active patent is invalid or not infringed. 21 U.S.C. § 355(j)(2)(B); 21 C.F.R. § 314.95. Under the Hatch-Waxman amendments, filing an ANDA with a paragraph IV certification is deemed to be a "highly artificial" act of infringement. 35 U.S.C. § 271(e)(2)(A); Eli Lilly & Co. v. Medtronic Inc., 496 U.S. 661, 678 (1990). This act of infringement permits the NDA holder and the patent owner to sue the ANDA applicant before the drug is placed on the market, which helps expedite the generic drug reaching the marketplace. Allergan, 324 F.3d at 1326-27.[4]

Because of the likelihood of litigation, the filing of a paragraph IV certification can be costly. Thus, to encourage the investment in ANDA generic drugs, Congress granted an economic incentive to the first generic company to file a paragraph IV certification. Pharmachemie B.V. v. Barr Labs., Inc., 276 F.3d 627, 629 (D.C. Cir. 2002). Under the Hatch-Waxman Amendments, the first drug manufacturing company to file a paragraph IV certification receives a 180-day period in which the first-filer is entitled to be the only provider of generic versions of the drug in the market place ("generic exclusivity period"). 21 U.S.C.

[4] If the patent holder brings an infringement suit in district court within 45 days of receiving notice of the paragraph IV certification, the suit triggers an automatic stay of the FDA approval of the ANDA for 30 months. 21 U.S.C. § 355(j)(5)(B)(iii). If the patent holder or NDA holder does not bring suit within 45 days after it has received notice, the unexpired patent itself will not bar the FDA's approval of the ANDA; rather, it is eligible for immediate approval. 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(f)(2).

§ 355(j)(5)(B)(iv)(I). Prior to 2003, this provision read as follows:

> If the [ANDA] contains a [paragraph IV] certification . . . and is for a drug for which a previous [ANDA] has been submitted [containing] such a certification, the [ANDA] shall be made effective not earlier than one hundred and eighty days after . . . the first commercial marketing of the drug under the previous ANDA.[5]

21 U.S.C. § 355(j)(5)(B)(iv)(I) (2001). In this case, the Court is asked to interpret this provision in light of the facts and circumstances of this case.

II. Factual Background

The facts in this case are not significantly in dispute and will only briefly be reviewed. On June 9, 2004, Teva filed a citizen petition with the FDA pursuant to 21 U.S.C. § 355; 21 C.F.R. § 10.30. Administrative Record ("A.R."), tab 1. The petition sought to have the FDA declare that the generic exclusivity period of a generic drug manufacturer could not be infringed upon by the brand-drug manufacturer's introduction into the market of its own brand generic drug. A.R., tab 1 at 1. The June 9, 2004 citizen's petition concerned a generic version of the drug Accupril®, which is administered to treat high blood pressure. Id. On July 2, 2004, the FDA responded to the petition and concluded that it did not have the authority under the FDCA to prevent brand generic drugs from being marketed during the 180-day marketing exclusivity period of the first ANDA filer. A.R., tab 4 ("FDA decision") at 2. Teva did not challenge the decision's application to Accupril ® in federal court, however, it now seeks to challenge the

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[5] In 2003, Congress passed the Medicare Prescription Drug Improvement and Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, § 1102(a)(1). This Act slightly altered the language of the FDCA exclusivity provision. Currently, 21 U.S.C. § 355(j)(5)(B)(iv)(I). The provision now reads:

> [I]f the application contains a certification described in [paragraph IV] and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

21 U.S.C. § 355(j)(5)(B)(iv)(I)(2003).

FDA's decision as applied to a different drug, Neurotin®, a drug administered to treat epilepsy, which contains the active ingredient gabapentin.

The plaintiffs seek relief in this case because they allege that Pfizer will begin selling a brand generic form of Neurotin® prior to the expiration of the generic exclusively period that will be shared by Teva and Purepac Pharmaceutical Co.[6] Compl. ¶ 3. The plaintiffs allege that the FDA has decided, through final agency action concerning Accuril®, that brand generic drugs may be sold prior to the expiration of the Generic Exclusivity Period regardless of whether the generic exclusivity period is based upon the text of the FDCA. Compl.¶ 2-3. Accordingly, the plaintiffs seek declaratory and injunctive relief declaring the FDA's denial of Teva's citizen's petition as arbitrary, capricious, an abuse of discretion, and a violation of the FDCA, 21 U.S.C. § 301 et seq., and the Administrative Procedure Act ("APA"), 5 U.S.C. § 701 et seq.

III. The Parties' Arguments

The plaintiffs raise a number of arguments in support of their motion for summary judgment. First, the plaintiffs contend that the challenged FDA decision is contrary to the purpose of the exclusivity period provision of the FDCA and is therefore arbitrary, capricious and contrary to law. Pls.' Mem. at 13-14. Specifically, the plaintiffs' opine that the purpose of the exclusivity provision is to provide a commercial incentive for ANDA applicants to undertake the paragraph IV certification process. According to the plaintiffs, if brand generic drugs are permitted to enter the market during the exclusivity period, this incentive is diminished. Pls.' Mem. at 15-16. Moreover, the plaintiffs assert that permitting brand generic drugs to enter the

[6] Purepac Pharmaceutical Company ("Purepac") is actually entitled to the 180 days of marketing exclusivity as the first paragraph IV filer. However, through a business arrangement, Purepac has agreed to waive its marketing exclusivity for generic gabapentin products with respect to Teva, thereby permitting Teva to sell generic gabapentin products before the expiration of the gabapentin generic exclusivity period. Compl. ¶ 92.

market during the exclusivity period benefits the NDA, not the ANDA, which is also contrary to the purpose of the exclusivity period provision of the FDCA. Id. at 17-19. Finally, the plaintiffs argue that both the FDA and courts have recognized that ANDA generic drugs and other brand generic drugs are legally and commercially equivalent, and therefore consistent with this determination, § 355(j)(5)(B)(iv) should be read to prohibit the marketing of both brand generic and ANDA generic drugs during the exclusivity period. Id. at 18-26. In the alternative, the plaintiffs seek a ruling from this Court that the FDA's interpretation of § 355(j)(5)(B)(iv) is inconsistent with prior agency and judicial precedent and therefore, this case should be remanded back to the FDA. Pls.' Reply at 13-32. The federal defendants counter that they have no statutory authority to delay the entry into the market of brand generic drugs. The FDA opines that the plain language of the statute at issue gives the FDA authority to delay entry into the market of ANDA generic drugs but not brand generic drugs. Def.'s Mem. at 9-12. Moreover, the federal defendants assert that the FDA's decision in this case is not inconsistent with prior FDA decisions and thus a remand is not appropriate. Id. at 12-16.

IV. Standard of Review

This Court may grant a motion for summary judgment under Federal Rule of Civil Procedure 56(c) if "the pleadings, depositions, answers to interrogatories and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). When ruling on a motion for summary judgment, this Court must view the evidence in the light most favorable to the non-moving party. Bayer v. United States Dep't of Treasury, 956 F.2d 330, 333 (D.C. Cir. 1992). "Likewise, when ruling on cross-motions for summary judgment, the court

shall grant summary judgment only if one of the moving parties is entitled to judgment as a matter of law upon material facts that are not genuinely in dispute." Barr, 238 F. Supp. 2d at 244. The parties agree, and this Court finds, that there are no material facts in dispute, and that the issues for resolution in this case are purely legal in nature. Thus, the entry of summary judgment for the party entitled to prevail as a matter of law is appropriate. Bayer, 956 F.2d at 333-34.

Under the Administrative Procedure Act, 5 U.S.C. § 706(2)(A), this Court may vacate a decision by the FDA only if the decision is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." This standard is highly deferential to the agency. See Citizens to Pres. Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971). Accordingly, "there is a presumption in favor of the validity of [the] administrative action." Bristol-Myers Squibb Co. v. Shalala, 923 F. Supp. 212, 216 (D.D.C. 1996).

The Supreme Court developed in Chevron U.S.A., Inc. v. Natural Res. Def. Council, 467 U.S. 837, 842-43 (1984), the standard for determining whether this Court should give deference to an agency's interpretation of a statute. As an initial matter, an agency's interpretation should only be given deference "'when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority.'" Dr. Reedy's Lab., Inc. v. Thompson, 302 F. Supp. 2d 340, 348 (D.N.J. 2003) (quoting United States v. Mead, 533 U.S. 218, 226-27 (2001); Robert Wood Johnson Univ. Hosp. v. Thompson, 297 F.3d 273, 281 (3d Cir. 2002)). The Court must employ a two-step analysis under Chevron. First, if the statute speaks clearly "to the precise question at issue," the Court must give effect to the unambiguously

expressed intent of Congress. Chevron, 467 U.S. at 842-43. Second, where the statute is "silent or ambiguous with respect to the specific issue," the Court must sustain the agency determination if it is based on a "permissible construction" of the statute. Id. at 843. A court does not need to reach this second step if, "employing traditional tools of statutory construction, [it] ascertains that Congress had an intention on the precise question at issue . . . ." Id. at 843 n.9. Chevron deference is frequently given to the FDA's interpretation of the FDCA, as well as its own regulations. See, e.g., Purepac Pharm. Co. v. Thompson, 354 F.3d 877, 883 (D.C. Cir. 2004); Serono Labs, Inc v. Shalala, 158 F.3d 1313, 1319-20 (D.C. Cir. 1998).

V. Legal Analysis

In determining whether Chevron deference should be accorded to the FDA's decision, this Court must first determine, by "employing traditional tools of statutory construction," whether "Congress had an intention on the precise question at issue . . . ." Chevron, 467 U.S. at 843 n.9. "The primary and general rule of statutory construction is that the intent of the lawmaker is to be found in the language that he has used." United States v. Goldenberg, 168 U.S. 95, 102-03 (1897). "[W]hen the statute's language is plain, the sole function of the courts—at least where the disposition required by the text is not absurd—is to enforce it according to its terms." Lamie v. United States Trustee, 540 U.S. 526, ____, 124 S.Ct. 1023, 1030 (2004). Thus, in such situations, "resort to legislative history is not appropriate in construing [the] plain statutory language." United States ex rel. Totten v. Bombardier Corp., 380 F.3d 488, 494 (D.C. Cir. 2004). If the plain meaning of the statute leads to an "absurd or futile result[], however, [the Supreme] Court has looked beyond the words to the purpose of the act." Perry v. Commerce Loan Co., 383 U.S. 392, 400 (1966). The District of Columbia Circuit has

held that "literal interpretation need not rise to the level of 'absurdity' before recourse is taken to the legislative history, . . . [but] there must be evidence that Congress meant something other than what it literally said before a court can depart from plain meaning." Engine Mfrs. Ass'n v. EPA, 88 F.3d 1075, 1088 (D.C. Cir. 1996).

Despite the plaintiffs lengthy argument that the FDA interpreted the statute in a manner that is inconsistent with the purpose of the FDCA and thus arbitrary, capricious, and contrary to law, this Court concludes that it need not go beyond the plain language of the statute to resolve the issues presented in this case. The statute at issue in this case states:

> If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection cont[ain]ing such a certification, the application shall be made effective not earlier than one hundred and eighty days after—
>
> (I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or
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> (II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed,
>
> whichever is earlier.

21 U.S.C. § 355(j)(5)(B)(iv) (2001). The statue, unambiguously on its face applies only to ANDA applications, not NDA applications. The statue makes clear that the FDA must delay approval of an ANDA until after the expiration of the 180 day exclusivity period for any "application" that "contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection cont[ain]ing such a certification." This subsection applies only to applications submitted under paragraph 2 of this

section. § 355(j)(5)(B)(iv). Paragraph (j)(2), in turn, explicitly applies only to "abbreviated application[s] for a new drug"—ANDAs. § 355(j)(2)(A). Accordingly, the statue only prohibits the FDA from approving subsequent ANDAs until after the 180 day exclusivity period has expired. Nothing in the statute provides any support for the argument that the FDA can prohibit NDA holders from entering the market with a brand generic drug during the exclusivity period. "Where, as here, the plain language of the statute is clear, the court generally will not inquire further into its meaning." Qi-Zhuo v. Meissner, 70 F.3d 136, 140 (D.C. Cir. 1995). Additionally, an entirely different subsection of § 355 addresses the approval of NDAs and nothing in that subsection prohibits NDA holders from introducing a brand generic drug in the market during an ANDA's exclusivity period. See § 355(c). Both § 355(c), regulating NDAs, and § 355(j), regulating ANDAs, painstakingly detail the approval process for each of the type of drugs. The Court cannot fathom any reason to apply § 355(j)(5)(B)(iv), a provision clearly addressing only ANDAs, to limit the introduction into the market of a generic drug of a NDA holder. Moreover, this Court does not believe that giving application to the clear language of the statute leads to an absurd result. Although it seems reasonable to assume that a plain reading of the statute will reduce the economic value of a ANDA holder's product during the generic exclusivity period and therefore diminish the incentive to file paragraph IV certifications,[7] Pls.' Mem. at 34-35, such

[7] The plaintiffs also seem to argue that it is not surprising that the statute is silent on the issue of whether the FDA can prohibit the sale of the brand generic drugs because the introduction of brand generic drugs into the market did not begin to occur until after the exclusivity provision was most recently revised. Pls.' Mem. at 32. Thus, since Congress was not confronted with the question presented in this case, it appears that the plaintiffs contend that this creates an ambiguity in the statue. Id. (citing PDK Labs Inc. v. DEA, 362 F.3d 786, 796 (D.C. Cir. 2004)). This argument has little merit since the plaintiffs themselves concede that they are aware of at least one instance of a brand generic drug entering the marketplace before the most recent statutory amendment. Id. at n.12. Moreover, PDK Labs does not support the plaintiffs argument. In PDK Labs, the court first recognized that "the 'fact that Congress may not have foreseen all of the consequences of a statutory enactment is not a sufficient reason for refusing to give effect to its plain meaning.'" Id. at 796. However, the PDK Labs court concluded that the plain

(continued...)

result does not rise to the level of absurdity, which would trigger this Court's obligation to look beyond the plain language of the statute.

Because the statue is clear and unambiguous in that it covers only ANDAs, the Court must "presume that Congress meant precisely what it said." Nat'l Public Radio, Inc. v. F.C.C., 254 F.3d 226, 230 (D.C. Cir. 2001). And so this Court "must give effect to the unambiguously expressed intent of Congress." Chevron, 467 U.S. at 842-43.[8] Accordingly, because the statute is clear, and the FDA's application of the statute is consistent with the plain meaning of the statute, its decision cannot be considered arbitrary, capricious or contrary to law. See, e.g., Belland v. Pension Benefits Guar. Corp., 726 F.2d 839, 844 (D.C. Cir. 1984) (rejecting argument that the defendants' decision was arbitrary, capricious, and an abuse of discretion because it "adhered to an express statutory purpose and complied with the statute's plain language.").

In the alternative, the plaintiffs argue that the Court should remand this case back to the FDA because its interpretation of the exclusivity period provision is inconsistent with prior interpretations of the FDCA that have been approved by the Supreme Court and courts of this Circuit. Pls.' Reply at 8-9. The plaintiffs raise a number of arguments to support this position. However, even assuming that the FDA has interpreted this provision of the FDCA in an

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[7](...continued)
meaning did not control because the statute at issue in that case was susceptible to more than one possible construction. Id. This is clearly not the situation here. The plain language of the statue at issue here is clear—it only applies to ANDAs.

[8] While a court should almost always defer to the plain and unambiguous language of the statute, in "rare cases [in which] the literal application of a statute will produce a result demonstrably at odds with the intentions of its drafters," the court should look to other sources to determine Congress' intent. United States v. Ron Pair Enterp., Inc., 489 U.S. 235, 242 (1989) (internal quotation omitted). The "burden in rebutting the presumption created by clear language is onerous: the [plaintiff] must 'show either that, as a matter of historical fact, Congress did not mean what it appears to have said, or that, as a matter of logic and statutory structure, it almost surely could not have meant it.'" Nat'l Public Radio, 254 F.3d at 230 (quoting Engine Mfrs. Ass'n v. EPA, 88 F.3d 1075, 1089 (D.C. Cir.1996)). The plaintiffs have simply failed to satisfy this burden.

inconsistent manner, this Court need not consider these arguments. Having already concluded that the exclusivity period provision is clear and unambiguous, this Court must give effect to Congress' intent regardless of the interpretation employed by the agency. America's Cmty. Bankers v. F.D.I.C., 200 F.3d 822, 834-45 (D.C. Cir. 2000) ("Under the Chevron standard, if Congress has directly spoken to the issue, and the intent of Congress is clear, then there is nothing for the agency to interpret, and the court must give effect to the unambiguous expression of Congress."). Therefore, because the FDA interpreted the statute consistent with the clear and unambiguous language used by Congress, it is immaterial that the FDA's interpretations may be inconsistent with its prior interpretations. Cf. Hemp Indus. Ass'n v. Drug Enforcement Admin., 357 F.3d 1012, 1018 n.6 (9th Cir. 2004) (declining to address the appellants' Regulatory Flexibility Act, 5 U.S.C. § 611, arguments because the court concluded that the plain language of the statue controlled). Accordingly, the plaintiffs' motion for summary judgment must be denied and the defendants' motion for summary judgment must be granted.

VI. Conclusion

For the foregoing reasons, this Court concludes that all the FDA has done is give effect to the plain and unambiguous language of 21 U.S.C. 21 U.S.C. § 355(j)(5)(B)(iv)(I). Accordingly, this Court must deny the plaintiffs' motion for summary judgment and grant the defendants' motion for summary judgment.

SO ORDERED this day of 23rd day of December, 2004.[9]

REGGIE B. WALTON
United States District Judge

[9] An Order consistent with the Court's ruling accompanies this Memorandum Opinion.